K121092

5. 510(K) SUMMARY

JUN 29 2012

DATE SUMMARY PREPARED: 05 February 2012

OWNER:
Baxter Healthcare Corporation
One Baxter Way
Westlake Village, CA 91362

CONTACT PERSON:
Niedre M. Heckman, MS, MPH, RAC
Manager, Regulatory Affairs
Baxter Healthcare Corporation
One Baxter Way
Westlake Village, CA 91362
Telephone: 805-372-4096
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DEVICE NAME:

Trade Name: FlowEase [Subcutaneous] Infusion Set
Common Name: IV Administration Set
Classification: 21 CFR 880.5440, Set, Administration, Intravascular
Class: Class II
Product Code: FPA

Table 5-1.
Predicate Devices

Predicate 510(k)	Device Name	Company	Clearance Date
K925362	Baxter SUB-Q-Set® Subcutaneous Infusion Set	Baxter Healthcare Corporation	08/28/1993
K102512	RMS Subcutaneous Needle Set	Repro-Med Systems, Inc.	05/20/2011
K020530	Evans SubQ	Evans Medical Inc.	04/29/2002

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DEVICE DESCRIPTION:

FlowEase [Subcutaneous] Infusion Set is a single use disposable device intended for the subcutaneous infusion of fluid medicines.

The FlowEase [Subcutaneous] Infusion Set consists of a copolyester blend Female ISO 594-2 Luer Lock Connector attached to a 24 inch length of non-DEHP PVC Tubing that is connected to a non-DEHP PVC Hub with wings. The Hub holds a 24-Gauge thin wall AISI 304 stainless steel Needle with a 90° bend at the distal end.

A medical grade UV-curable acrylated urethane Adhesive is placed on the outside bend of the needle to secure it within the Hub.

The FlowEase [Subcutaneous] Infusion Set also includes a HDPE Bantam Slide Clamp used to start and stop fluid flow. The needle is supplied covered with an LDPE Needle Protector, and the Female Luer Lock Connector is covered with an ABS Male ISO 594-2 Luer Lock Cap.

The FlowEase [Subcutaneous] Infusion Set will be marketed with a 24-Gauge thin wall needle that will be available in three needle lengths: 6 mm, 9 mm, and 12 mm. Each set will be packaged with a commercially available dressing, used to hold the device in place on the patient.

The FlowEase [Subcutaneous] Infusion Set is provided Gamma sterilized and non-pyrogenic. Each Set is packaged individually in a medical grade thermoformed copolyester tray with a Tyvek® lid, labeled according to needle size.

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STATEMENT OF INTENDED USE:	Intended for the subcutaneous infusion of fluid medicines.
TECHNOLOGICAL CHARACTERISTICS:	The FlowEase [Subcutaneous] Infusion Set is substantially equivalent to the predicate devices with regard to technological characteristics, performance, and intended use.
ASSESSMENT OF NONCLINICAL DATA:	Baxter Healthcare Corporation conducts risk analysis according to the requirements of ISO 14971:2007 Medical Devices-Application of Risk Management to Medical Devices. Device performance and safety have been verified through functional and biocompatibility testing.
CONCLUSIONS:	The FlowEase [Subcutaneous] Infusion Set is substantially equivalent to the predicate devices. Testing against established standards and guidelines for its intended use demonstrate that the proposed device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Niedre Heckman
Manager, Regulatory Affairs
Baxter Healthcare Corporation
One Baxter Way
Westlake Village, California 91362

JUN 29 2012

Re: K121092
Trade/Device Name: FlowEase Subcutaneous Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: April 6, 2012
Received: April 10, 2012

Dear Ms. Heckman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

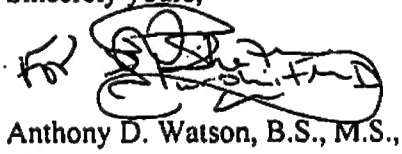
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: FlowEase [Subcutaneous] Infusion Set

Indication(s) for Use:

Intended for the subcutaneous infusion of fluid medicines.

Prescription Use: ☑ 21 CFR 801 Subpart D

AND/OR

Over-the-Counter Use: ☐ 21 CFR 801 Subpart C

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Richard C Chapman 6/28/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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